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Applicants: BALDWIN *et al.*

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Date of Signature: December 3, 2002

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Assistant Commissioner for Patents
Washington, D.C. 20231

RESPONSE TO REQUIREMENT for ELECTION of SPECIES UNDER 37 CFR §1.121

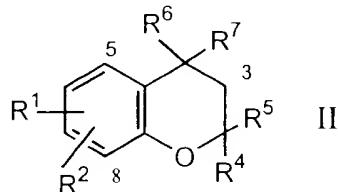
Dear Sir:

This is a reply to the Office communication mailed June 3, 2002 (paper number 14), which set a one month period for response. In light of the accompanying fee and request for an extension of time, a reply to the Action is due December 3, 2002, and this response is timely filed.

In light of a previous requirement for restriction and a subsequent amendment to add claims 39-49, claims 4-7 and 38-49 are pending in the application. The present Office Action requires Applicants to elect a single disclosed species for prosecution on the merits, to which the claims shall be restricted if no generic claim is found allowable. More specifically, the Action requires Applicants to "elect, for purposes of a search, a single, fully-defined compound. That is, all atoms and bonds of each and every variable group should be defined. . . . The instant species election requires that one - and only one- compound be elected; the elected species should contain no variable groups."

With regard to an election of species, Applicants elect the species defined as:

A compound of the formula:



wherein:

R¹ is -OCH₂CO₂H;

R^2 is -H;

R^4 and R^5 taken together are $-(CH_2)_2-S(O)_{0-2}-(CH_2)_2-$;

one of R^6 and R^7 is -H and the other is -H or $-N(CH_2)_{1-6}R^{14}R^{15}$;

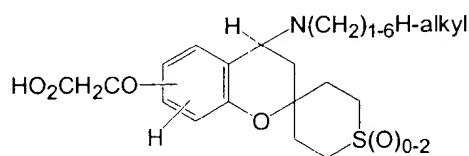
R¹⁴ is -H; and

R^{15} is alkyl,

or a pharmaceutically acceptable salt thereof.

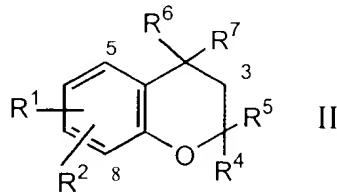
As required, each of the variables in generic Formula II, *i.e.*, R^1 through R^7 , has been defined. With respect to the definition of R^6 and R^7 , the variables R^{14} and R^{15} , have also been defined.

The elected species is represented by the structure:



The elected variable definitions are underlined and bolded in the following copy of generic claim 4.

4. A compound of the formula:



wherein:

R¹ is OH, O(CH₂)₁₋₂OH, OCH₂CO₂H, CO₂H, O-Z-C(O)NH(CH₂)₁₋₆R¹⁷ or OCH₂-4-Phe-C(O)NH(CH₂)₁₋₆R¹⁷;

R² is H or lower alkyl;

R³ is H, alkyl, aryl, or arylalkyl;

R⁴ and R⁵ are each independently H, lower alkyl, or substituted lower alkyl where the substituents are 1-3 alkoxy, aryl, substituted aryl, carboalkoxy, carboxamido or di-loweralkylamido; or

R⁴ and R⁵ taken together are -(CH₂)_n-, -(CH₂)₂-O-(CH₂)₂-, -CH₂-O-(CH₂)₃-, -(CH₂)₂-NR⁸-CH₂)₂-, -CH₂-NR⁸-(CH₂)_m-, -(CH₂)₂CH(NHR⁸)(CH₂)₂-, -CH₂CH(N-loweralkyl)(CH₂)₂CHCH₂-
-(CH₂)₂-S(O)₀₋₂-(CH₂)₂-, or

one of R⁶ and R⁷ is H and the other is H, OH, or N(CH₂)₁₋₆R¹⁴R¹⁵, or

R⁶ and R⁷ taken together are , with the proviso that when

R¹ is -OH and R² is -H, R⁶ and R⁷ are not -H and -OH or when taken together are not ; R⁸ is H, COOR⁹, CONHR¹⁰, CSNHR¹¹, COR¹², SO₂R¹³, lower alkyl, aryl lower alkyl, heteroaryl, or heteroaryl lower alkyl, wherein aryl is optionally substituted with 1-3 substituents selected from lower alkyl, lower alkoxy, halo, CN, NH₂, COOH, CONH₂, carboalkoxy, and mono- or di-lower alkylamino and wherein heteroaryl is a mono- or bicyclic heteroaromatic ring system of 5 to 10 members including 1 to 3 heteroatoms selected from O, N, and S and 0-3 substituents selected from halo, amino, cyano, lower alkyl, carboalkoxy, CONH₂, and S-lower alkyl;

R⁹ is lower alkyl, aryl, aryl lower alkyl, heteroaryl, aryl substituted by 1-3 substituents selected from alkyl, alkenyl, alkoxy, methylene dioxy, and halo, or a 5- to 6-membered heterocyclic ring containing O or N as a heteroatom, wherein heteroaryl is a heteroaromatic ring of 5 to 6 members including 1 to 2 heteroatoms selected from O, N, and S and 0-2 substituents selected from lower alkyl, dialkylamino, lower alkoxy, and halo;

R¹⁰ and R¹¹ are each independently lower alkyl, aryl, aryl lower alkyl, or aryl substituted by 1-3 substituents selected from lower alkyl, halo, alkoxy and haloalkyl;

R¹² is lower alkyl, aryl, heteroaryl, aryl lower alkyl, heteroaryl lower alkyl, a 5- or 6-membered heterocyclic ring containing 1-2 heteroatoms selected from O, S, and N, a 5- or 6-membered heterocyclic ring containing 1-2 heteroatoms selected from O, S, and N-lower alkyl, or aryl substituted with 1-3 substituents selected from lower alkyl, alkoxy, halo, sulfamoyl, lower alkyl sulfamoyl, cyano, and phenyl;

R¹³ is lower alkyl, aryl, or aryl substituted with 1-3 substituents selected from lower alkyl, alkoxy, halo, CN, and haloalkyl;

R¹⁴ is H; alkyl; alkyl substituted by 1-3 alkoxy, S-lower alkyl, sulfamoyl, halo, alkylsulphonamido, or arylsulphonamido; alkenyl; alkynyl; aryl; substituted aryl; heteroaryl; substituted heteroaryl; heterocycloalkyl; -CH₂NR¹⁶C(O)R¹⁶; -C(O)NR¹⁶R¹⁶; -CH₂OC(O)R¹⁶; or -CH₂SC(O)R¹⁶;

R¹⁵ is H, alkyl, -C(O)X, -C(S)X, or -C(NCN)NR³R³;

R¹⁶ is lower alkyl, substituted lower alkyl, aryl, or substituted aryl;

R¹⁷ is H; alkyl; alkyl substituted by 1-3 alkoxy, S-lower alkyl, sulfamoyl, halo, alkylsulphonamido, or arylsulphonamido; alkenyl; alkynyl; aryl; substituted aryl; heteroaryl; substituted heteroaryl; heterocycloalkyl; -CH₂NR¹⁶C(O)R¹⁶; -C(O)NR¹⁶R¹⁶; -CH₂OC(O)R¹⁶; or -CH₂SC(O)R¹⁶;

X is alkyl, aryl, arylalkyl, O-loweralkyl, or -NR³R³;

Z is -(CH₂)₁₋₆-, optionally substituted with 1-3 lower alkyl; -CHR²-; -Phe-CH₂-, where Phe is optionally mono-substituted with halogen, lower alkyl, or alkoxy; or heteroarylene-(CH₂)-;

m is 2 or 3; and

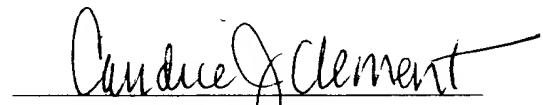
n is 4-9;

or a pharmaceutically acceptable salt thereof.

With regard to the remaining pending claims, claims 38-39 and 41 read on the elected species.

Respectively submitted,

December 3, 2002



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